

#### REMARKS

Reconsideration of the present application in view of the above Amendments and following remarks is respectfully requested. Claims 1-8 and 12-21 are currently pending. Claims 1, 8, 12, and 21 have been amended to expedite prosecution of specific embodiments of Applicants' invention, without acquiescence to any rejection and without prejudice to prosecuting any removed subject matter in a related divisional, continuation, or continuation-in-part application. No new matter has been added to the application. Support for the amendments may be found throughout the specification, for example, at page 7, lines 7-10; page 9, lines 26-31; page 16, lines 1-7; and page 30, lines 22-28.

#### ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner rejected claims 1-8 and 12-21 under 35 U.S.C. § 112, first paragraph, asserting that the claimed subject matter is not commensurate in scope with the disclosure. The Examiner asserts that the specification does not enable a person skilled in the art to make and use a method comprising administering proteosomes and hemagglutinin (HA) antigen at any ratio greater than 8:1.

Applicants respectfully traverse this rejection and submit that the specification provides sufficient guidance to teach a person skilled in the art how to make and use methods to elicit an immune response against influenza and to treat influenza in a subject by administering proteosomes and HA antigen at a ratio greater than 8:1. A person skilled in the art need not make every composition at all possible ratios greater than 8:1 to practice the claimed methods. Furthermore, given the teachings in the application and the level of skill in the art, a person skilled in the art could, readily and without undue experimentation, identify and characterize a method that comprises administering a composition comprising proteosomes and HA antigen at a ratio greater than 8:1 (*see In re Wands*, 858 F.2d 731, 736 (Fed. Cir. 1988) ("Enablement is not precluded by the necessity for some experimentation such as routine screening.")). Nevertheless, without acquiescence to the rejection and solely to expedite prosecution of the application, the claims have been amended to recite that the method comprises administering proteosomes and HA at a ratio between 2:1 and 8:1. Applicants submit that the specification provides abundant guidance, including working examples, that teach a person skilled in the art how to make and

use, readily and without undue experimentation, methods for treating influenza infections by administering a composition comprising proteosomes and HA antigen at a ratio between 2:1 and 8:1 (see specification, for example, at page 7, lines 7-10; page 9, lines 26-31; page 16, lines 1-7; page 30, lines 22-28).

**DEFINITENESS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

The Examiner rejected claims 1-8 and 12-21 under 35 U.S.C. § 112, second paragraph, asserting that the claims are indefinite. The Examiner asserts that a recitation that a composition comprises proteosomes and HA antigen at a ratio of greater than 2:1 does not set an upper limit and that the metes and bounds of the claimed subject matter cannot be determined.

Applicants respectfully submit that in view of the Amendments to the claims submitted herewith, without acquiescence or prejudice, the basis for the rejection has been obviated. The present claims are directed, in pertinent part, to methods to elicit an immune response against influenza and to treat influenza in a subject, wherein the method comprises administering proteosomes and HA at a ratio between 2:1 and 8:1 (*see, e.g.*, specification at page 7, lines 7-10; page 9, lines 26-31; page 16, lines 1-7; page 30, lines 22-28).

Accordingly, the present claims particularly point out and distinctly claim certain embodiments of Applicants' invention, complying with the definiteness requirements under 35 U.S.C. § 112, second paragraph. Applicants therefore respectfully request that this rejection be withdrawn.

Applicants respectfully submit that claims 1-8 and 12-21 in this application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. In the event that the Examiner believes a teleconference will facilitate prosecution of this application, the Examiner is invited to telephone the undersigned at 206-622-4900.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,  
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